ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114308424-58-01/F Helsinki, 8 September 2015

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For C16-18-(even numbered, saturated and unsaturated)-alkylamines, CAS No 1213789-63-9, registration number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for C16-18-(even numbered, saturated and unsaturated)-alkylamines, CAS No 1213789-63-9, submitted by [redacted] (Registrant). The scope of this compliance check is limited to the requirements regarding the identification of the substance (Annex VI, Section 2 of the REACH Regulation).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year. On 4 February 2015, it was communicated to the Registrant by ECHA, that this decision would not take into account any updates after 13 March 2015, the deadline for updating. However, the Registrant updated his registration on the next working day (16 March 2015) with the submission number [redacted] after the expiry of the deadline for updating. Thus, exceptionally, for this decision, ECHA does not take into account any updates after 16 March 2015.

This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 26 September 2013.

On 25 September 2014 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. That draft decision was based on submission number [redacted].

By 3 November 2014 the Registrant did not provide any comments on the draft decision to ECHA.

On 16 March 2015 the Registrant updated his registration dossier with the submission number [redacted].

The ECHA Secretariat considered the Registrant's update. On basis of this information, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 23 July 2015 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

Information in the technical dossier related to the identity of the substance

Pursuant to Articles 41(1)(a), 41(3), 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

Name or other identifier of the substance (Annex VI, 2.1).

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **15 December 2015**.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

Information in the technical dossier related to the identity of the substance

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

Name or other identifier of the substance (Annex VI, 2.1.)

"Name or other identifier of the substance" is an information requirement as laid down in Annex VI, Section 2.1 of the REACH Regulation. The name and other identifiers are used to identify the substance in an unambiguous manner and are therefore fundamental for substance identification. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant identified the registered substance as of a Unknown or Variable composition, Complex reaction products or Biological materials (UVCB) substance. However, the composition reported in section 1.2 of the registration dossier and the corresponding analytical data are not consistent with this identification.

More specifically, the Registrant reported *C16-18-(even numbered, saturated and unsaturated)-alkylamines* as the chemical name for the registered substance in the IUPAC name field of the registration dossier. Whilst this chemical name reports, in generic terms, different groups of alkyl amine constituents and corresponds to a UVCB substance, it does not accurately reflect the identity and predominance of the constituents actually listed in the

peak table given in the report of chromatographic analysis attached in section 1.4 of the registration dossier.

On 16 March 2015 the Registrant updated his registration dossier with the submission number [redacted]. The Registrant has reported in section 1.2 of the updated registration dossier that the substance contains constituents *C18-(unsaturated)-alkylamine*, *octadecan-1-amine* (i.e. C18 saturated), and *hexadecan-1-amine* (i.e. C16 saturated) at a maximum concentration above 10%. No other constituents are present with a maximum concentration value higher than 10%. However, the chemical name of the registered substance reported in the IUPAC name field of the registration dossier indicates that the substance contains *C16-(unsaturated)-alkylamine* at a maximum concentration above 10%. Therefore, the inclusion of *C16-(unsaturated)-alkylamine* in the chemical name does not accurately reflect the identity and predominance of the constituents present in the substance based on information provided in sections 1.2 and 1.4 of the registration dossier.

ECHA concludes that the name and numerical identifiers reported in section 1.1 are not representative of the substance registered.

Therefore the Registrant is requested to revise the name, molecular formula and other identifiers of the registered substance.

The Registrant shall note that the CAS entry used in the registration dossier (CAS number 1213789-63-9) can cover substances that contain even numbered alkyl chains and both even and odd alkyl chains. However, the registration dossier can cover only one substance and it shall thus be clearly identifiable for ECHA from the information in the dossier to which substance the registration refers. This information must be consistent throughout the registration dossier.

Regarding how to report the requested information in IUCLID the following applies:

- The revised chemical name shall be included in the IUPAC name field in Section 1.1 of IUCLID.
- Regarding the name to be reported in section 1.1, the substance will be named based on each constituent, of defined alkyl chain length, present at concentration ≥10% (based on the maximum concentration of the concentration range). For this purpose constituents shall be grouped based on alkyl chain length and separated into saturated linear, saturated branched and unsaturated constituents (e.g. C16 saturated, C16 unsaturated, C18 saturated, C18 unsaturated, etc.). The groups of consituents to be considered for naming shall compose at least 80%(w/w) of the substance.
- The revised name, based on the guidance in the above bullet point, shall be reported in the IUPAC name field in section 1.1 of IUCLID. The appropriate CAS entry shall be included in the "CAS information" field, if available. Where the current CAS entry (CAS number 1213789-63-9) does not identify the registered substance, it should be reported under the "Related CAS information" field in IUCLID section 1.1. Similarly where the current list number (627-034-4) does not correctly identify the registered substance, it will need to be revised. For technical reasons the Registrant is requested at this stage, not to remove or revise the list entry in the updated dossier. As this registration is linked to this EC entry in REACH-IT, the IT system will not accept the updated dossier as an update when the EC entry has changed. The Registrant shall instead include the following in the "Remarks field" of the reference substance: "*This EC entry is not appropriate to identify the registered substance.*

This identifier cannot be modified in the present registration at this stage for technical reasons."

Further information on how to report the chemical name, the molecular and structural formulae, other identifiers and the description of the manufacturing process is available in "Data submission manual Part 18 – How to report the substance identity in IUCLID 5 for registration under REACH" (version: 2.0, July 2012), available on the ECHA website.

IV. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on ECHA's internet page at http://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[1] by Guilhem de Seze, Head of Unit, Evaluation

[2] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.